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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER				
SASAKI, SHOGO				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/560,214

Applicant(s)

OHMAN ET AL.

Examiner

Shogo Sasaki

Art Unit

1797

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/26/2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 3,5,15,16,18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-14,17,19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/083)
- Paper No(s)/Mail Date 12/9/05
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Amendments to claims filed on 10/20/2008 are acknowledged.

Election/Restrictions

2. Applicant's election with traverse of Group I reply filed on 10/20/2008 is acknowledged. In instant case, since claim 1 is not applicant's contribution over prior art (see rejection of claim 1 below), there exists lack of unity *a posteriori*. The traversal is on the ground that the examiner has not established that a serious burden exists if restriction is not required. This is not found persuasive because establishing lack of unity between inventions provides the ground for restriction under U.S.C. 372. In addition, inventions require a different field of search and this establishes that a serious burden exists on the examiner if restriction is not required.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 15, 16 and 18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group/Invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 10/20/2008.
4. Applicant's election of Species A in the reply filed on 1/26/2009 is acknowledged. Applicant's amendments to claims are acknowledged. However the amendments will not result in withdrawal of the original species election requirement between some of the species. Claims 2 (Species A) and 3 (Species B) as newly claimed are still two different species of claim 1. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Species D-F are withdrawn from the requirement for the purpose of this office action.
5. Claims 3 and 5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim.

Claim Interpretation

6. Regarding claim 2, the limitation "each flow path is connected to a sink of said two or more sinks" was interpreted to mean that the multiple flow paths are each connected to corresponding sinks; instead of the multiple flow paths being connected to one of the multiple sinks and other sinks have no connections to any flow path.
7. Regarding claim 9, it is suggested to positively set forth "a sub-section within said at least one sink" as part of the claimed subject matter. "Said at least one sink is adapted for division into subsection" was interpreted to mean at least one sink has an area, in which any portion thereof can be considered a subsection.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
9. Claim 11 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding the alternative expression in claim 11, the multiple recitations of "or" and "and" among the selection renders said claim indefinite. Appropriate correction is required.

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B **and** C." Other form "wherein R is A, B, C **or** D" shall also be considered proper. Note: The alternative expression in claim 19 is proper.

Claim 17 provides for the use of the device of claim 1, but, since the claim does not set forth any steps involved in the method, it is unclear what method applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. Note: Should applicant amend claim 17 to include a special technical feature (a special process of using the device of claim 1, such processes in claim 15 and 16), it will be grouped with Group II or III; or it will be grouped separately from Groups I, II and III.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 2, 4, 6-14, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Regnier et al. (US 6156273).

Regarding claims 1, 2, 4, 6-14, 17 and 19, Regnier et al. disclose a device for handling a liquid sample comprising; and a method of using the same (column 3, line 36-column 12, line 51):

- at least one flow path (Fig. 6: 107, 108, 109, 114, 116);
- at least one zone (Fig. 6: 99, 118);
- a transport zone (Fig. 6: 112);
- at least one sink (Fig. 6: 100) comprising an area having projections (Fig. 1B, 14; or Fig. 2A-2F: These are present on the 100 side as well.) substantially vertical to its surface; wherein said at least one sink has a capacity (The fluid flow in the direction of the arrow 110. Therefore the side 102 must be the source and the side 100 will have to be the sink. The sink has an area therefore it possesses a capacity.);

- wherein said at least one flow path is two or more flow paths (Fig. 6: 107, 108, 109, 114, 116); said at least one sink is two or more sinks (The side 100 in Fig. 6 include channels 104, which is equivalent to 12 on the side 102 (Fig. 1A; column 5, line 61; and column 11, line 31). Any configuration/interconnections of the channel 104 may effectively form variety of sinks.); each flow path is connected to a sink of said two or more sinks (The flow path 109 are connected to corresponding portions of sink having square cross-sectional projections.);
- wherein said at least one flow path is in fluid connection with said at least one sink and is a flow path formed as a capillary open channel (Fig. 6: 107, 108, 109, 114, 116);
- wherein said at least one flow path is in fluid connection with said at least one sink, and wherein said at least one flow path comprises areas having substantially vertical projections (Fig. 1 A and 6: The flow path 107-108-109 provides 3 different types of polygonal vertical projections.);
- wherein said vertical projections have different cross sections in different zones of said at least one flow path projections (Fig. 1 A and 6: The flow paths 107-108-109 provide 3 different types of polygonal vertical projections.);
- a design feature (Fig. 1 A; 2A-F and 6: The flow paths 107-108-109 provide 3 different types of polygonal vertical projections; and the sinks provides tetragonal vertical projections or polygonal vertical projections.); and
- wherein said design feature is a set of vertical projections having different cross sections in different zones of said at least one flow path (Fig. 1 A; 2A-F and 6: The flow paths 107-108-109 provide 3 different types of polygonal vertical projections; and the sinks provides tetragonal vertical projections or polygonal vertical projections.).

Regarding claims 1, 2, 4, 6-10 and 14, recitations directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus

from the prior art. The process limitations do not have patentable weight in an apparatus claim.

12. Claims 1, 2, 4, 6-14, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Bhullar et al. (US 6451264).

Regarding claims 1, 2, 4, 6-14, 17 and 19, Bhullar et al. disclose a device for handling a liquid sample comprising; and a method of using the same (abstract):

- at least one flow path (Fig. 1: 16, 18, 24, 26, 28);
- at least one zone (Any area in said fluid pathways may be considered a zone.);
- a transport zone (Any portion of said fluid pathways may be considered transport zones.);
- at least one sink (Fig. 1: 20) comprising an area having projections (Fig. 5, 37, 39; and column 4, lines 57-63) substantially vertical to its surface (These leads are formed via etching/lithography, thus they must protrude from the bottom surface of the site 20.); wherein said at least one sink has a capacity (The fluid flows to the testing site 20 (column 4, lines 8-13). Therefore the inlet 14 must be the source and the site 20 will have to be the sink. The sink has an area therefore it possesses a capacity.);
- wherein said at least one flow path is two or more flow paths (Fig. 1: 16, 24, 26, 28); said at least one sink is two or more sinks (Fig. 1: 20); each flow path is connected to a sink of said two or more sinks (Fig. 1);
- wherein said at least one flow path is in fluid connection with said at least one sink and is a flow path formed as a capillary open channel (Fig. 1: 16, 24, 26, 28; column 4, lines 22-26);
- wherein said at least one flow path is in fluid connection with said at least one sink, and wherein said at least one flow path comprises areas having substantially vertical projections (Fig. 2 and 3; column 5, lines 1-39);
- wherein said vertical projections have different cross sections in different zones of said at least one flow path projections (Fig. 2 and 3; column 5, lines 1-39);

- a design feature (Fig. 2 and 3; column 5, lines 1-39); and
- wherein said design feature is a set of vertical projections having different cross sections in different zones of said at least one flow path (Fig. 2 and 3; column 5, lines 1-39).

Regarding claims 1, 2, 4, 6-10 and 14, recitations directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art. The process limitations do not have patentable weight in an apparatus claim.

13. Claims 1, 6-14, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohman et al. (IDS: WO 3103835).

Regarding claims 1, 6-14, 17 and 19, Ohman et al. et al. disclose a device for handling a liquid sample comprising; and a method of using the same (abstract):

- at least one flow path (Fig. 10);
- at least one zone (Fig. 10, zones 1-3);
- a transport zone (Any zone in said path way may be considered a transport zone, since the fluid flows through them.);
- at least one sink (Fig. 9, The exit with pad 10; and page 11, lines 8-17) comprising an area having projections (Fig. 9, The exit where 10 is laid on effectively becomes the flow sink as disclosed; and it has vertical projections in that particular area; page 11, lines 1-7) substantially vertical to its surface; wherein said at least one sink has a capacity (The sink has an volume of absorbing material, therefore it possesses a capacity.);
- wherein said at least one flow path is in fluid connection with said at least one sink and is a flow path formed as a capillary open channel (Fig. 11 and 12: 1);
- wherein said at least one flow path is in fluid connection with said at least one sink, and wherein said at least one flow path comprises areas having substantially vertical projections (Fig. 11 and 12: 1);

- wherein said vertical projections have different cross sections in different zones of said at least one flow path projections (page 5, lines 11-13);
- a design feature (page 5, lines 11-13); and
- wherein said design feature is a set of vertical projections having different cross sections in different zones of said at least one flow path (page 5, lines 11-13).

Regarding claims 1, 6-10 and 14, recitations directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art. The process limitations do not have patentable weight in an apparatus claim.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 2 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohman et al. (IDS: WO 3103835).

Regarding claims 2 and 4, Ohman et al. disclose all of the limitations as set forth above.

Ohman et al. does not teach wherein said at least one flow path is two or more flow paths; said at least one sink is two or more sinks; each flow path is connected to a sink of said two or more sinks.

However the claim 2 is no different than having two devices of claim 1. (Unless applicant meant the multiple flow paths are connected to one of the multiple sinks and other sinks have no connections to any flow path.)

It would have been obvious to one having ordinary skill in the art at the time of the invention to have two pathways connected to two different sinks, since mere duplication of parts has no patentable significance, since it involves only routine skill in the art.

Regarding claims 2 and 4, recitations directed to the manner in which a claimed apparatus is intended to be used does not distinguish the claimed apparatus from the prior art. The process limitations do not have patentable weight in an apparatus claim.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shogo Sasaki whose telephone number is (571)270-7071. The examiner can normally be reached on Mon-Thur, 10:00am-6:30pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SS

2/25/09

/Brian R Gordon/

Primary Examiner, Art Unit 1797